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Subcommittee to Update the 1999 NRC Arsenic Review

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The Office of Advocacy of the U.S. Small Business Administration welcomes the opportunity to provide testimony on the arsenic in drinking water standard before the National Research Council's (NRC) Subcommittee to Update the 1999 Arsenic in Drinking Water Report. The Office of Advocacy was established by Congress pursuant to Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Over the last two years, we have worked closely with the Environmental Protection Agency (EPA) in the development of the proposed and final regulations for arsenic in drinking water. This includes a review of the draft arsenic regulation in a formal proceeding

under the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1999, involving the Office of Management and Budget and EPA.

We wrote to EPA Administrator Whitman in March commending the agency's decision to review the arsenic standard of 10 ppb that was promulgated in January 2001. We found that the 10 ppb was not justified given the available scientific and cost information; thus, we support the EPA's plan to update and review these issues. Hundreds of small water companies, found predominantly in rural America, would be faced with dramatically high treatment costs to meet the arsenic drinking water standard set by the Environmental Protection Agency (EPA). We welcome a review of the latest science, and a review of the 2000 EPA Science Advisory Board (SAB) Report by the new subcommittee, as requested by EPA.

In this testimony I will address several issues involving sound science and scientific integrity. First, we suggest that the NRC revise the current composition of the panel to reflect a fair and balanced group of scientists, and reflect the requisite range of expertise. Second, we strongly urge the NRC to reconsider its decision to withhold information on critical bias and conflict of interest issues in order to inform the public on these issues. Third, we address the importance of the NRC subcommittee following the EPA charge to closely focus on the science, and avoid addressing policy issues. Fourth, we discuss the consequences of improper science determinations: the large costs that would be imposed on rural water systems and rural water consumers to address an arsenic risk of questionable magnitude. The science determination is very important here because any given standard denies local communities the choice of spending their money on reducing arsenic risks (real or otherwise) or spending money on other pressing local needs, such as education or public health. These costs could easily exceed hundreds of dollars per household in the smallest water systems.

I. The NRC Should Reformulate the Composition of the Provisional Arsenic Subcommittee and Reveal Information about Potential Bias to Satisfy the Public Right to Know

We hope that the NRC process will yield a sound and unbiased review of the risks from arsenic in drinking water. Considering the intense political scrutiny associated with the arsenic issue, it is even more critical that the NRC carefully establish a panel of scientists that everyone can agree reflects a diversity of expertise, and avoids actual and potential conflicts of interest.

The 1997 FACA amendments requires the NRC to solicit comments on the makeup of all subcommittees that advise the Federal government. In particular, we are concerned with the balance of views on the provisional panel. Further, we are suggesting several scientists who provide expertise in areas that are missing from the current provisional subcommittee. These scientists have an array of backgrounds, and were recommended to us by persons from industry, academia and government. We also find that the inclusion of some of the provisional scientists are not consistent with the 1992 NRC Policy on Disclosure of Personal Involvements and Other Matters Potentially Affecting Committee Service (hereafter, "NRC Policy") for eliminating bias and avoidance of conflict of interest. Lastly, in order to comment fully on the scientific integrity of the provisional panel, we need additional information on the background of the provisional members that the NRC inexplicably continues to withhold from the public.

A. Members Who Served on the 1999 Subcommittee Have A Conflict of Interest and Should Not Serve on the 2001 Subcommittee.

We provided detailed comments on this issue on May16th to the NRC (see enclosure). We believe that, based on the NRC Policy, those scientists who served on the 1999 subcommittee should not be participants in the review and update of the 1999 NRC Report. The NRC finds that "an individual should not serve as a member of a subcommittee engaged in a study in which a critical review and evaluation of the individual's own work ... is expected to be a central purpose of the study, but such an individual may provide relevant information to the study." NRC Policy at 4.

Consistent with these principles, we are also looking for a diversity of opinions and expertise in this panel, whose members are not burdened by bias or conflict of interest. The NRC guidance specifically suggests that such persons may more appropriately present "relevant information" to the subcommittee. Therefore, we recommend that the NRC exclude those participants in the 1999 panel, because a large part of the task of this subcommittee is to review the earlier NRC subcommittee work.

The 1997 Federal Advisory Committee Act (FACA) Amendments specifically require that "[t]he Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed, unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable,..." Exclusion of the previous NRC panel members would be consistent with this legal requirement.

B. Members Who Have Expressed A Position on the Arsenic Standard Should be Excluded or the Panel Should Be Rebalanced To Include Others With a Contrary View.

A separate issue is presented by the issue of subcommittee member bias. Unlike the EPA policy barring scientists who have public positions on an issue because of bias, the somewhat more lenient NRC policy finds that bias is "not necessarily disqualifying." NRC Policy at 3. Instead, the NRC may seek to present a "balance of potentially biasing backgrounds or professional or organizational perspectives." NRC Policy at 2. However, the NRC panelists are chosen behind closed doors, without the disclosure of the conflicts of interest and bias statements made by provisional panelists.

The bias questionnaires require the disclosure of public positions by all provisional members, but we do not have access to these disclosures. Frankly, we think that this is a significant defect in the public notice and comment procedure, because any potential subcommittee member should be willing to reveal his or her public statements or professional affiliations in order to inform these public comments. We are unable to comment fully on these provisional appointments without this information. In the case of one of the provisional members, we understand that Dr. Michael Kosnett has expressed an opinion that a 20 ppb standard was "not acceptable" in an article published by Reuters Health on October 13, 1999, and that he has expressed similar views on other public occasions. We assume that this will be confirmed in the papers filed with the Council and suggest that either he be excluded, or that a more appropriate balance be established on the subcommittee.

In addition, we note that of all five returning subcommittee members, none were among the four who expressed concern about being pressured by NRC staff in the writing of the report, nor were they among those who expressed doubts about the validity of the Taiwan data risk extrapolations. In combination with the nomination of Dr. Kosnett, who has publicly supported the final 10 ppb standard now being questioned, there appears to be a serious question concerning the balance of the present composition of the provisional subcommittee appointees.

In the EPA SAB process, EPA requires disclosure to the agency of all public statements. It is my understanding that the Freedom of Information Act (FOIA) would permit public disclosure of this information, because such information, by definition, would not invade personal privacy (the only applicable exception to FOIA). Unfortunately, under the 1997 NRC legislation exempting the organization from the Federal Advisory Committee Act requirements, the NRC is specifically exempted from the FOIA requirements with respect to "agents" of the NRC in the context of providing advice to Federal agencies, which includes these provisional panelists. However, neither the NRC nor anyone else has explained why any ethical panelists seeking appointments from the prestigious National Academy of Sciences would keep their public positions hidden from the public, nor why the NRC would insist upon keeping this information hidden. (The NRC simply cites its confidential procedures, without providing any justification as to how this procedure does not compromise scientific integrity.) We have asked for this information, and, to date, our request has been denied.

C. An Additional Comment Period Is Warranted After the New Information Is Provided to Protect Scientific Integrity: Information About Public Positions and Contracts with Federal Agencies

As described above, we ask that the information about the public views and professional affiliations be made public, such that, if any one of the provisional members has a potential bias or conflict of interest, an additional comment period should be allowed. The scientific integrity of the subcommittee can best be protected if there is full public disclosure. Otherwise, the public would not be protected from potential bias, conflicts of interest, or errors on the part of NRC or the sponsoring agency, EPA.

Furthermore, in order to fully inform the commenters, the NRC should publicly disclose contracts with NRC or the sponsoring agency, with respect to arsenic or any other environmental policy contracts, as these facts are revealed in the confidential questionnaires submitted by potential subcommittee members. Since the SAB regularly requires disclosure of these potential conflicts of interests, the NRC should not keep this information private. The research support information is sought for the express purpose of identifying potential sources of bias and conflict of interests, and it is in the public interest for commenters to have access to this information. We understand that Federal agencies must disclose information about persons who receive government funds; therefore, logically, the provisional appointees should not object to this procedure. Again, because such information is not protected by privacy laws, EPA would make this information available under FOIA upon request. Considering the significance of this information to the scientific integrity of this and all other panels, why should the NRC, in providing advice to Federal agencies on important science issues, withold such information from the public?

In the case of the previous arsenic subcommittee, some have suggested that scientists who received funding from NRC or EPA had a conflict of interest, and that this bias was reflected in some of the stronger language in the final report (see below). Irrespective of the merits of this contention, the public has the right to know these affiliations in providing comments to the NRC, and the NRC should forthrightly address these conflict of interest issues in order to preserve the scientific integrity of the process and ensure compliance with the integrity requirements of the 1997 FACA Amendments governing this process.

II. Accurate and Careful Report Language is Critical to Achievement of the Goal of Communicating Sound Science - Two Examples of Careless Attention to Science and the Scientific Charge of the 1999 NRC Arsenic Panel

I want to stress the importance of careful and deliberate attention to the scientific issues in the preparation of the report, including special focus on the specific EPA charge to the subcommittee to engage in the scienctific, rather than policymaking issues. While we do applaud the previous NRC report for its extremely thorough treatment of the topic, there were two significant lapses in the previous report. I will discuss these two very controversial passages in the report, their implications, and urge the subcommittee to be vigilant to avoid such future problems.

First, I will address the oft-quoted "1-100 risk estimate" from the 1999 NRC subcommittee report. Despite the report's statement that it wasn't writing a formal risk assessment, its unwillingness to endorse the use of the Taiwan data, and numerous statements about uncertainties, the NRC, in a single sentence made one apparently casual remark about total cancer risk. Among the findings of S. 635, the Arsenic Standard Reinstatement Act, introduced in March by Senator Dodd, is the statement that "the National Academy of Sciences has determined that drinking water containing 50 parts per billion of arsenic`could easily' result in a 1-in-100 risk of cancer." This claim was repeated by, among others, the New York Times and the Natural Resources Defense Council, despite the fact that this claim was subsequently refuted by the EPA in its Fall 2000 Notice of Data Availability and the Morales (2000) study cited by EPA. The NODA finds that the risk of lung and bladder cancer, using the NRC methodology, was approximately to 1-in-1000 at the 50 ppb level (see tables 2 and 3, assume linear extrapolation from 20 ppb to 50 ppb). The 1-in-100 claim has been repeated by others without challenge on many occasions. It is critical that the NRC ensure that its work is crafted carefully because of the effect such statements can have on Congress, the EPA, and public policy makers.

Even more disturbing is the interpretation taken by the Congressional sponsors of HR 1252, the Arsenic Reduction in Drinking Water Act in March 28th: "According to National Academy of Sciences estimates, one out of 100 people who drink water containing 50 parts per billion of arsenic will get cancer (based

on drinking two liters of water per day over the course of a lifetime). That's an unacceptably high cancer risk." People reading this sentence in areas with high arsenic levels will be frightened unnecessarily by these statements, which were derived through the inappropriate interpretation of the single incorrect NRC sentence, which appears contrary to the entire thrust of the report. Not only is the earlier NRC statement now refuted by EPA, the statement was converted into an alarmist statement that 1 out of 100 Americans drinking this water will get cancer, without any consideration of uncertainty or the other qualifications throughout the report. The NRC report should be without reproach, and carefully drafted, as appears evident to other readers of the remainder of the report.

The latest twist on sound science comes in the form of a new bill with the catchy title, Get Arsenic Out of Our Drinking Water Act, HR 1413, which was introduced in April. As the scientists know, the available treatment techniques can remove 95% or more of the arsenic, but not all of the arsenic from the water. Will the next bill be named, "Get Inconvenient Science Out of Our Environmental Bill Titles"? The level of public discourse on science and environmental issues is discouragingly low. The NRC certainly can't prevent others from distorting its own work, but it shouldn't negligently contribute to the problem.

We would be remiss to omit mention of the single most quoted sentence in the NRC report. "…[I]t is the subcommittee's consensus that the current [Maximum Contaminant Level] MCL for arsenic in drinking water of 50 ug/L does not achieve EPA's goal for public health protection and therefore requires downward revision as promptly as possible." NRC at 254. First, the NRC panel was not charged with making any recommendation on the standard (some have alleged that they were pressured by NRC staff to do so, but we need not reach this conclusion to have concerns about the process). Second, like the previous one sentence excursion, this sentence appears not to belong in the report for two reasons. This sentence is inconsistent with all the language about the report not being a "formal risk assessment", not sanctioning the use of the Taiwan data, and substantial language about uncertainty, including an uncertainty estimate of "several orders of magnitude" (what does this say about the 1/100 risk sentence?).[1,2] In addition, none of the other statements in the NRC report include consideration of costs, benefits, feasibility, or other considerations required in the policy determination of the appropriate MCL under the Safe Drinking Water Act. The statement about the standard was inconsistent with the EPA charge to make recommendations about science, not policy.[3]

What are the lessons to be drawn from these two sentences? Both the NRC and the subcommittee should pay strict attention to the subcommittee charge, and be careful to make specific and well documented determinations in the report. In fairness to the NRC, while we have not reviewed the previous report with fine tooth comb, with the exception of these two statements, we found the report to be a superlative piece of work. It was as if the two statements were an after-thought to all the carefully caveated and supported work found elsewhere in the report.

III. Local Communities May be Unable to Fund Other More Important Public Health Needs If the Arsenic Risks Are Overestimated; The Federal Maximum Contaminant Level (MCL) Denies Local Choice to those Communities Whose Water System Exceeds the MCL.

While it is outside the function of the Subcommittee to consider directly the appropriate setting of the MCL, it is important for the subcommittee to understand fully the consequence of setting the MCL. The federal MCL mandates treatment if the local water system exceeds that particular level, costing in excess of $300/year/household for the smallest systems, according to EPA's own cost estimates. Others have used different assumptions, primarily about the number of entry points requiring treatment, and the cost of treating residual wastes, among other factors, to raise those estimates by factors of approximately three to five. These are substantial costs on individual homeowners and their respective communities.

If the community must spend ratepayer money on arsenic treatment, that local money is unable to fund other important local needs. If the MCL is high enough, the local community has the choice of making the decision among competing health and other priorities. If the MCL is lower than the local arsenic level, the Federal government would be making that choice for the community. Therefore, it is critical that the EPA receive the best unbiased advice regarding the estimated risks of arsenic in drinking water and the related level of uncertainty, given the magnitude of these costs on small communities across the country.

Footnotes

1. These are some of the statements in the report that demonstrate the inconsistency of the remainder of the report with this particular recommendation. The NRC Report indicated it was "important to emphasize again that the results are not to be interpreted as a formal risk assessment, or as an endorsement of these data for the use of risk assessment for arsenic in drinking water." NRC at 230. "As seen in Table 10-8, the resulting estimates of the excess lifetime risk of cancer can change fairly substantially by several orders of magnitude." NRC at 247. "Finally some factors … could not be taken into account quantitatively in this chapter. These factors include poor nutrition and low selenium concentrations in Taiwan, genetic and cultural characteristics, and arsenic intake from food." NRC at 250. "Regardless of the data set that is ultimately used for the arsenic risk assessment, the subcommittee recommends that a range of feasible modeling approaches be explored. The final calculated risk should be supported a range of analyses over a fairly broad range of assumptions. Performing a sensitivity analysis ensures that the conclusions do not rely heavily on any one particular assumption." NRC at 250. "No human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drinking water at the current MCL …results in an increased of cancer or noncancer effects. NRC at 253. "Some factors, such as poor nutrition and arsenic intake from food, might affect assessment of risk in Taiwan or extrapolation of results in the United States." NRC at 254. All of these statements, individually and collectively, are inconsistent with the conclusion that 50 ppb standard is too high and needs to be corrected promptly.

2. However, to the extent the Subcommittee is qualified to address issues, not within the EPA charge, that it believes it must address, and that it has adequate information to make such judgments, it should feel free to do so. However, the casual and inconsistent manner in which a few sentences appeared in the final 1999 NRC report damaged rather than enhanced the final product.

3. Finally, the panel certainly did not have the appropriate documentation upon which to base such a determination, even if the panel were qualified in the policy areas to be addressed.